K092435

510(k) Summary

MAR - 9 2010

K_____ Submission Date: August 4th, 2009

1. **Submitter Information:** AEGIS Regulatory, Inc. - Robert T. Wagner
1131 Anthem View Lane
Knoxville, TN 37922
Tel.: 865-982-5552
Email: bob@fdalistingconsultants.com

For Manufacturer: King Tai Holdings Ltd.
Attn: Mr. Li Shek King
No. 26 Gongie Industrial Zone
Xixiang Road, BoAn District
Shenzhen, China
Tel.: (01186) 755 279 11430

2. **General Information**

2.1 Classification Name: IRP – Powered Inflatable Tube Massager

2.2 Common/Usual Name: Inflatable Leg Massager

2.3 Proprietary Names: Verseo Air Pressure Leg Massager

2.4 Classification: Class II

2.5 Classification Number: 890.5650

3. **Description:**

The Verseo Air Pressure Leg Massager is an inflatable cuff that wraps around the lower leg and is secured by a Velcro strap, operated via AA – battery-powered electronic touch-pad controller with colored LED's denoting pressure increase, decrease and automatic massage function. Brochure manual is attached hereto.

4. **Intended Use:**

Indications for Use: The Verseo Air Pressure Massager is intended to temporarily relieve minor muscle aches and pains and to temporarily increase circulation to the treated areas. The Verseo Air Pressure Massager simulates kneading and stroking of tissues with the hands by use of an inflatable pressure cuff.

5. Substantial Equivalence to Predicate Device(s):

This device is substantially equivalent to the following predicate devices, which are currently in safe and effective commerce:

1. K040905 – Wellness/Jolivette (Tohkai Precision Ind. Ltd.)
2. K030437 – Relaxor Perfect... (Salton, Inc.)
3. K071596 – Portable Air Mass...(Nihon Seimitsu Sokki Co. Ltd.)

6. Performance Standards:

These devices have been tested under and are in compliance with performance standards that have been established for such devices under Section 878 of the Federal Food, Drug, and Cosmetics Act. All electrical and radiological products made by the applicant have been OSHA/NRTL listed, and have received constituent marks.

7. Labeling:

As appear in the User's Manuals and on the device itself – Numerous technical warnings and advisements to insure proper use and maintenance.

8. Statement of Safety and Effectiveness:

The information in this 510(k) submission was used to support the safety and effectiveness of this device with respect to its cited predicates.

9. Over-The-Counter Variance Request:

As identical predicates of this device have been in safe and effective applications by layperson users, Over-The-Counter Variance is requested.

10. Design and Use of the Device(s):

Is the device intended for prescription use?	NO
Is the device intended for over-the-counter use?	YES
Are its components derived from a tissue or other biologic source?	NO
Is the device provided sterile?	NO
Is the device intended for single use?	NO
Is the device a reprocessed single use device?	NO
Does the device contain a drug?	NO
Does the device contain a biologic?	NO
Does the device use software?	NO
Does the submission include clinical information	NO
Is the device implanted?	NO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

King Tai Holdings Ltd.
% AEGIS, Inc.
Mr. Robert T. Wagner
1131 Anthem View Lane
Knoxville, TN 37922

MAR 09 2010

Re: K092435
Trade/Device Name: Verseo Air Pressure Massager
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
Dated: February 22, 2010
Received: March 8, 2010

Dear Mr. Wagner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092435

Device Name: Verso Leg Massager – Produced by King Tai Holdings Ltd.

Indications For Use:

The Verseo Air Pressure Massager is intended to temporarily relieve minor muscle aches and pains and to temporarily increase circulation to the treated areas. The Verseo Air Pressure Massager simulates kneading and stroking of tissues with the hands by use of an inflatable pressure cuff.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092435